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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,491	01/16/2002	Tommy J. Shane	TOM8	7699

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EXAMINER

NGUYEN, NGOC YEN M

ART UNIT	PAPER NUMBER
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1754

DATE MAILED: 03/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/050,491

Applicant(s)

SHANE ET AL

Examiner

Ngoc-Yen M. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-18 are, drawn to a method for controlling the hypochlorite/hypochlorous acid balance, classified in class 423, subclass 472+.
- II. Claims 19-20 are, drawn to an apparatus for producing hypochlorous acid, classified in class 422, subclass 189+.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another materially different process such as for producing chlorine dioxide.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Todd Deveau on January 9, 2004 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-18. Affirmation of this election must be made by applicant in replying to this

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Office action. Claims 19-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 2-3, it is unclear if "the control stream" is referred to the control stream before or after the introduction of the chlorination agent.

In claim 9, it is unclear if the limitation in the parentheses is positively required.

In claim 10, it is unclear if the acid is required in addition to the carbon dioxide or instead of the carbon dioxide?

In claim 11, the "system" in the preamble should be changed to the "process".

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waggoner (6,019,905) in view of Shane (5,514,264).

Waggoner '905 discloses a method for providing a sanitized aqueous medium for a water delivery system to a dental patient, the steps comprising:

- (a) providing a dental unit for use in dental treatment;
- (b) delivering a stream of water to said dental unit from a source of potable water containing hypochlorous acid and hypochlorite and free chlorine in an amount of about 0.1 ppm or more;
- (c) providing an acidifier selected from the group consisting of inorganic acids, organic acids, and acid esters; and
- (d) incorporating said acidifier into the water delivered to said water delivery system in an amount to reduce the pH of the water delivered to the water delivery system to a value of about 3.2 or less to provide a substantially enhanced hypochlorous acid content sufficient to eliminate the viability of a mature biofilm produced by the bacteria *Pseudomonas aeruginosa* (note claim 1).

The acidifier is incorporated into said water stream in an amount to provide a ratio of hypochlorous acid to hypochlorite ion of at least 50:1 (note claim 2).

The acidifier is selected from the group consisting of acetic acid, citric acid, phosphoric acid, tartaric acid, etc. (note claim 3).

Waggoner '905 discloses that hypochlorous acid is formed by the chlorination of water. Hypochlorous acid is a relatively weak acid exhibiting a pK_a of 7.53. Thus, in municipal water systems which are near neutral in pH, one-half of the chlorine is present as a hypochlorous acid (note column 7, lines 12-51).

The difference is Waggoner '905 does not disclose a step of injected the acid into the water at high pressure.

Shane '264 discloses a process for treating potable or waste water so as to reduce the pH of the water by injecting carbon dioxide into the potable or waste water (note column 1, lines 10-14). In the process, carbon dioxide gas at an elevated pressure is injected into carrier water, also at an elevated pressure. The carrier water-carbon dioxide solution, still at an elevated pressure, then is injected into the water to be treated (note column 1, lines 59-64). The solution feed system of Shane '264 does not extended contact area and overall contact time can be reduced (note column 2, lines 54-67).

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to use the method of injecting an acid into a water stream in Waggoner '905 at high pressure as suggested by Shane '264 because such method is more efficient and compact. It would also have been obvious to one of ordinary skill in the art at the time of the invention was made to use carbon dioxide instead of the acid listed in Waggoner '905 because Shane '264 teaches that carbon dioxide can lower the pH of the water stream just as the acid can.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devine et al (5,720,438) in view of Waggoner (6,019,905) and Shane '264.

Devine '438 teaches that microbiocidal activity of chlorine is largely attributed to hypochlorous acid (HOCl). Hypochlorite ion (OCl) possesses about 1/80th the germicidal capacity of hypochlorous acid (HOCl). The chemical reaction which causes disassociation of hypochlorous acid to the less microbiocidal form hypochlorite ion, chlorine, and various sodium salts is dependent on pH. As the pH increases, more hypochlorite ion (OCl) is formed and the microbiocidal activity decreases. As the pH decreases, the concentration of hypochlorous acid increases and the microbiocidal activity increases. Hypochlorous acid is the "microbiocidal" component of the disassociated end products of sodium hypochlorite. The production of hypochlorous acid and resultant microbiocidal activity is at its greatest when the pH is in the range of from 4 to 6 (note column 2, lines 7-21).

Devine '438 utilizes a sodium hypochlorite (NaOCl) solution adjusted to a pH of from about 4.0 to 6.0 to increase the hypochlorous acid component and significantly increase the microbiocidal activity of the disinfectant (note column 2, lines 30-34).

Devine does not specifically disclose (1) the step of introducing a chlorination agent into the control stream to increase the concentration of hypochlorous acid and hypochlorite in the control stream and (2) the step of adding carbon dioxide or an acid to the water stream at high pressure.

For difference (1) Waggoner '905 is applied as stated above to teach that it is common in the art to form a solution which contains both hypochlorous acid and

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hypochlorite (note step b of claim 1). In order to form such solution, a chlorination agent must be added to a water stream as required in the instant claim.

It would have been obvious to one of ordinary skill in the art at the time of the invention was made use a solution which contains both hypochlorous acid and hypochlorite, as suggested by Waggoner '905, for the process of Devine '438 because such solution is known in art and its pH can be lowered to increase the amount of hypochlorous acid by the process described of Devine '438.

For difference (2), Shane is applied as stated above.

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to use the method of injecting an acid into a water stream in Devine '438 at high pressure as suggested by Shane '264 because such method is more efficient and compact. It would also have been obvious to one of ordinary skill in the art at the time of the invention was made to use an acid as listed in Waggoner '905 in addition to the carbon dioxide as disclosed in Shane '264 because they are both effective as agents to lower the pH of the water stream, and combining two or more materials disclosed by the prior art for the same purpose to be used for the same purpose has been held to be a prima facie case of obviousness, see *In re Kerkhoven*, 205 USPQ 1069.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ngoc-Yen M. Nguyen whose telephone number is (571) 272-1356. The examiner is currently on Part time schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Stan Silverman can be reached on (571) 272-1358. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed (571) 272-1700.



Ngoc-Yen M. Nguyen
Primary Examiner
Art Unit 1754

nmn

March 22, 2004